

Regarding claims 13 and 34, the Examiner objects to the recitation of the term "near" in the phrase "positioning at least one magnet near an outside wall of the sample processing vessel".

To overcome the Examiner's objection, Applicants have amended claims 13 and 34 to more clearly point out and claim this step. Applicants have changed the "positioning" step to read "positioning at least one magnet towards the sample processing vessel to hold the magnetic particles against an inside wall of the sample processing vessel by magnetic force". Support for the amendment can be found, for example, on page 9, third paragraph, and page 10, final paragraph. Applicants submit that this amendment clarifies the claims. No narrowing has occurred by this amendment. In fact, the amendment broadens the scope of these claims by removing an unnecessary restriction on the location of the magnet.

Regarding claim 17, the Examiner takes the position that the phrase "may be" renders the claim indefinite because it is considered unclear whether the limitations following the phrase are a part of the claimed invention.

Applicants have amended claim 17 in order to respond to this objection.

Regarding claim 19, the Examiner takes the position that the phrase " μ -metal" renders the claim vague and indefinite.

This objection is respectfully traversed. The phrase " μ -metal" is well-known in the art. Attached are two internet print-outs providing a few details on μ -metals. These selections are but a few of the thousands of pages revealed from a simple search on the Google™ search engine. Applicants respectfully submit that this objection should be withdrawn.

Regarding claims 20 and 21, the Examiner objects to the phrases "about 0.5 g to 5 g" in claim 20 and "about 1 g to 4 g" in claim 21.

Applicants assume that the Examiner merely wants these claims to be rewritten to resemble claim 29 (which was not rejected). Claim 29 contains the phrase "about 70° to about 95°C". Applicants note the use of the term "about" in describing both temperatures. Thus, Applicants assume that the Examiner simply wants Applicants to include a second "about" to modify the second numeral in the range. To this end, Applicants have amended claims 20 and 21.

Claim 20 is objected to for use of the phrase "around room temperature or higher".

Applicants have amended claim 28 to use the term "above room temperature". Support can be found on page 17, third paragraph, of the specification.

Claims 13-18, 22-28 and 30-35 are rejected under 35 U.S.C. § 102(e) as being anticipated by Reeve (U.S. Patent No. 5,523,231). The Examiner takes the position that Reeve shows all of the limitations of the rejected claims.

Applicants discuss the Reeve patent, as follows.

Applicants draw the Examiner's attention to Figure 2 and the accompanying description on column 6, lines 4-33. According to this section of the Reeve patent, a solution is provided containing bacteriophage or other virus particles. The particles are incubated with magnetic beads, and the particles aggregate around the suspended magnetic beads. Thereafter, a magnetic field is applied to the solution, which draws the complex of magnetic beads and particles to the bottom or side of the reaction vessel. Thereafter, the supernatant is removed from the reaction

vessel, and a second fluid is introduced into the vessel. During this part of the treatment, the magnetic field is removed. Thereafter, the magnetic field is reapplied to separate the magnetic beads and the virus particles (which are now dissolved in solution). The supernatant containing the dissolved particles is collected with a pipette while the beads are held against the bottom or side of the tube by the magnetic field. According to Figure 2, the purified dissolved particles are thereafter ready for DNA extraction.

Comparing the procedure described in Reeve with claim 13, Applicants note that the "re-suspending" step is different than what is disclosed in Reeve. This is due to the fact that in claim 13, the sample processing vessel is shaken. There is no shaking of the sample processing vessel disclosed in Reeve. In addition, while Figure 2 of Reeve indicates that the purified virus particles are ready for DNA extraction, there is no specific disclosure in the specification of lysing the particles and isolating the nucleic acids from the lysis mixture, as claimed in claim 13. While Reeve discloses the lysis of cells and isolation of nucleic acids, these lysis and isolation steps are conducted in the presence of the magnetic particles. In fact, the magnetic particles are used for the isolation of the nucleic acids from the lysis mixture. See, for example, Figures 1a, 1b and 3 and the examples.

Page 15 of the present specification indicates that the shaking step is an important feature of the invention. Thus, Applicants respectfully submit that the Reeve patent cannot anticipate the present invention. In addition, there is no suggestion of the important feature of the present invention, i.e., the shaking step. For this reason, Reeve cannot render obvious the present invention.


Regarding claim 34, similar comments apply. Claim 34, however, contains the additional steps of warming the lysis mixture and cooling the lysis mixture to assist in the isolation of the nucleic acids. Reeve discloses chilling the reaction solution. However, this chilling is used to promote aggregation of the nucleic acids or virus particles with the magnetic beads. See page 4, lines 17-21. Applicants do not note any disclosure or suggestion of warming the lysis mixture, as claimed in claim 34. Thus, for this additional reason, the present invention is not anticipated by Reeve.

Claims 20, 21 and 29 are rejected under 35 U.S.C. § 103(a) as being obvious over Reeve. The Examiner takes the position that the limitations in these claims represent no more than routine optimization which would have been obvious to those of ordinary skill in the art.

Applicants note that these dependent claims are patentable at least by virtue of their being dependent on the patentable features discussed above. Since Reeve does not disclose or suggest the claimed invention, these dependent claims are also patentable.

In the event this paper is not timely filed, applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, along with any other additional fees which may be required with respect to this paper, referencing attorney docket no. 101614-00001.

Respectfully submitted,


Richard J. Berman
Registration No. 39,107

Customer No. 004372
ARENT FOX KINTNER PLOTKIN & KAHN, PLLC
1050 Connecticut Avenue, N.W., Suite 400
Washington, D.C. 20036-5339
Tel: (202) 857-6000; Fax: (202) 638-4810
Enclosures: Internet Print-Outs

MARKED-UP COPY OF AMENDED CLAIMS

13. (Amended) A method of isolating nucleic acids from biological compartments of a fluid sample comprising the steps of:

incubating the sample in a sample processing vessel with magnetic particles which magnetic particles are capable of binding with the biological compartments;

positioning at least one magnet [near an outside wall of] towards the sample processing vessel [such that the magnet holds] to hold the magnetic particles against an inside wall of the sample processing vessel by magnetic force;

removing the remaining fluid, from which the biological compartments have been separated, from the sample processing vessel;

introducing a second fluid into the sample processing vessel;

resuspending the magnetic particles in the second fluid by eliminating the magnetic force which held the magnetic particles against the inside wall of the sample processing vessel, and shaking the sample processing vessel;

lysing the biological compartments to form a lysis mixture; and

isolating the nucleic acids from the lysis mixture.

17. (Amended) The method of claim 13, wherein the nucleic acids to be isolated are transferred to [a] another vessel [from which they may be pipetted] which is configured to receive a pipette.

20. (Amended) The method of claim 13, wherein each magnet has a mass of about 0.5 g to about 5 g.

21. (Amended) The method of claim 13, wherein each magnet has a mass of about 1 g to about 4 g.

28. (Amended) The method of claim 27, wherein the lysis mixture is warmed to a temperature [of around] above room temperature [or higher].

34. (Amended) A method of isolating nucleic acids from biological compartments of a fluid sample comprising the steps of:

incubating the sample in a sample processing vessel with magnetic particles which magnetic particles are capable of binding with the biological compartments;

positioning at least one magnet [near an outside wall of] towards the sample processing vessel [such that the magnet holds] to hold the magnetic particles against an inside wall of the sample processing vessel by magnetic force;

removing the remaining fluid, from which the biological compartments have been separated, from the sample processing vessel;

introducing a second fluid into the sample processing vessel;

resuspending the magnetic particles in the second fluid by eliminating the magnetic force which held the magnetic particles against the inside wall of the sample processing vessel, and shaking the sample processing vessel;

lysing the biological compartments to form a lysis mixture; and

warming the lysis mixture; and

cooling the lysis mixture under conditions that make it possible to isolate or hybridize the nucleic acids to be isolated or detected.